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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,330	08/22/2001	Carl Johan Friddle	LEX-0221-USA	9990

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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,330	FRIDDLE ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) 6 is/are withdrawn from consideration.

5)☒ Claim(s) 2-5 is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Comply

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth below:

A. Nucleic acid sequences of SEQ IDs NOs:1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 24 and 26 that were submitted in both printed and in computer-readable forms with the application each contain coding sequence regions - open reading frames - that have not been set forth in accord with 37 CFR 1.822(c)(2) and (c)(3) which state:

> (2) The bases in a nucleotide sequence (including introns) shall be listed in groups of 10 bases **except in the coding parts of the sequence.** Leftover bases, fewer than 10 in number, at the end of noncoding parts of a sequence shall be grouped together and separated from adjacent groups of 10 or 3 bases by a space.
>
> (3) **The bases in the coding parts of a nucleotide sequence shall be listed as triplets (codons). The amino acids corresponding to the codons in the coding parts of a nucleotide sequence shall be typed immediately below the corresponding codons.** Where a codon spans an intron, the amino acid symbol shall be typed below the portion of the codon containing two nucleotides.

(Emphases supplied). **No coding region in any nucleotide sequence provides the triplet codons and there is no depiction of the encoded amino acids beneath their corresponding codons as required by 37 CFR 1.822(c)(3).**

B. The first 16 amino acids of SEQ ID NO:2 are absent from the printed copy of the sequence listing submitted with the application. The original CRF includes the initial 16 amino acids of SEQ ID NO:2, thus Applicant's "Verified" Statement filed with the application stating that "the contents of the paper and original computer readable copies of the Sequence Listing are the same" is untrue.

Applicant's attention is also directed to 37 CFR 1.825 and to MPEP §2426.

In response to this communication, Applicant MUST supply each of the following:

1) a new, printed, copy of the sequence listing wherein ALL nucleotide sequences are set forth as required by 37 CFR 1.822(c)(3) and wherein ALL amino acids in each amino sequence are set forth, as an Amendment to the specification with directions to replace the originally-submitted printed form of the Sequence Listing with the new printed form of the Sequence Listing,

2) a new copy of the sequence listing in computer readable form [CRF] on a properly-labeled diskette wherein ALL nucleotide sequences are set forth as required by 37 CFR

1.822(c)(3), and wherein ALL amino acids in each amino sequence are set forth, together with directions to replace the originally-submitted CRF with the new CRF, and,

3) a Statement pursuant to 37 CFR 1.821(f) attesting to the identity of the disclosure of both the printed and computer-readable forms of the sequence listing.

Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 451-amino acid sequence set forth in SEQ ID NO:2, classified in class 530, subclass 350.

2. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 297-amino acid sequence set forth in SEQ ID NO:4, classified in class 530, subclass 350.

3. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 486-amino acid sequence set forth in SEQ ID NO:6, classified in class 530, subclass 350.

4. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,222-amino acid sequence set forth in SEQ ID NO:8, classified in class 530, subclass 350.

5. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,219-amino acid sequence set forth in SEQ ID NO:10, classified in class 530, subclass 350.

6. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,216-amino acid sequence set forth in SEQ ID NO:12, classified in class 530, subclass 350.

7. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,213-amino acid sequence set forth in SEQ ID NO:14, classified in class 530, subclass 350.

8. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,235-amino acid sequence set forth in SEQ ID NO:16, classified in class 530, subclass 350.

9. Claim 1, drawn in part to a nucleic acid sequence encoding a polypeptide having the 1,232-amino acid sequence set forth in SEQ ID NO:18, classified in class 530, subclass 350.

10. Claim 1, drawn in part to, and claims 2-5 drawn to, a nucleic acid sequence encoding a polypeptide having the 1,252-amino acid sequence set forth in SEQ ID NO:20 or the related 1,240-amino acid sequence set forth in SEQ ID NO: 22, classified in class 530, subclass 350.

11. Claim 1, drawn in part, and claim 6 drawn to, a nucleic acid sequence encoding a polypeptide having the 1,907-amino acid sequence set forth in SEQ ID NO:25, classified in class 530, subclass 350.

Inventions of Groups 1-12 lack unity of invention, each with the other, because as many as 12 genera of separate and distinct polynucleotide products are described by the claims and each is disclosed to have a separate and distinct coding capacity for a native polypeptide having, respectively, the amino acid sequences of SEQ IDs NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22 and 25 which are not disclosed to have any common structural feature.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 1-12 is not required for other of Groups 1-12 , restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

During a telephone conversation with Mr. Peter Seferian on August 19, 2002, a provisional election was made **with** traverse to prosecute the invention of Group 10, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-5 are examined herein to the extent that they describe a nucleic acid sequence encoding an amino acid sequences set forth in SEQ ID NO:20 or in SEQ ID NO: 22, and claim 1 is withdrawn in part, and 6 is withdrawn specifically, from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention to the extent that they describe nucleic acid sequences encoding the amino acid sequences set forth in SEQ IDs NOs:2, 4, 6, 8, 10, 12, 14, 16, 18 and 25.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting "[a]n isolated nucleic acid molecule comprising at a nucleotide sequence encoding an amino acid sequence" because the added preposition "at" has no subsequent clause or phrase that states a location. An amendment that deletes "at" from line 2 of claim 1 will overcome this rejection.

Allowable Subject Matter

Claims 2-5 are allowable because they are free of rejections under the first and second paragraphs of 35 U.S.C. §112 and are also free of the prior art of record. They are not rejected under the first paragraph of 35 U.S.C. §112 because any nucleic acid sequence encoding SEQ ID NO:20 is member of the genus of nucleic acid sequences isocoding with SEQ ID NO:19, i.e., their codons correspond to each amino acid at each position in SEQ ID NO:20 yet may differ so long as the same amino acid sequence is encoded. Applicant need disclose no other species of this limited genus because every member thereof can be designed with standard software available to artisans for the past two decades. Clauses (a) and (b) of claim 2 are stated in the conjunctive, rather than the disjunctive, and nearly all, if not all, nucleotide sequences that are isocoding with SEQ ID NO:19 of clause (a) will meet the structural limitations of clause (b). Applicant is thus considered to have been in possession of the genus of nucleic acid molecules that encodes the nucleic acid sequence of SEQ ID NO:20, whether or not they hybridize to SEQ ID NO:19 under high stringency conditions, and all species of this genus of nucleic acid molecules are enabled where they may be readily designed and prepared by the artisan, as are all members of the genus of nucleic acid molecules that encode SEQ ID NO:22 enabled where they may also be readily designed and prepared by the artisan.

Isolated nucleic acid molecules of claim 1 comprising a nucleotide sequence encoding either SEQ ID NO:20 or SEQ ID NO:22 - subject matters examined herein - as well as the subject matters claims 2-4 and the subject matter of claim 5 are all free of the prior art

60/233,796 - as well as the subject matters claims 2-4 and the subject matter of claim 5 are all free of the prior art of record which fails to disclose or suggest a nucleotide sequence encoding SEQ ID NO:20 or SEQ ID NO:22. Made of record with Applicant's Information Disclosure Statement and cited in the Search Report for the corresponding application PCT/US01/26148, Smith, the EMBL/GenBank/DDBJ database entry having Accession No. AC016043, discloses a nucleotide sequence region of a human genomic DNA segment wherein a contiguous array of 295 nucleotides shares 100% identity with the nucleic acid sequence of SEQ ID NO:19 from position 678 through 872, assuring hybridization of this genomic DNA segment with the complement of SEQ ID NO:19 under stringent conditions, as well as hybridization of the complement of the genomic DNA segment with SEQ ID NO:19 under stringent conditions, according to clause (b) of claim 2. But Smith cannot anticipate or render obvious subject matters of claims 1-4 because each of these claims requires that a claimed nucleic acid molecule encode the entire, integral, amino acid sequence of SEQ ID NO:20 and the DNA segment of Smith identified in the Search Report could encode no more than 65 amino acids, only 5% of the 1,252 amino acids of sequence set forth in SEQ ID NO:20. The DNA segment of Smith is neither a cDNA nor a mRNA, and Smith fails to teach that any region constitutes an exon encoding any portion of a human protease or that exons are present elsewhere within their disclosed chromosomal DNA segment that might be transcribed and spliced to form a human protease-encoding mRNA.

The nucleic acid sequence encoding the ADAM-TS1/Meth-1 protease of Casas et al. made of record with Applicant's Information Disclosure Statement and cited in the Search Report for the corresponding PCT application, is also not prior art to a claimed invention because the ADAM-TS1/Meth-1 protease taught by Casas et al. has only 15.8% nucleic overall acid sequence identity with the amino acid sequence of SEQ ID NO:20 herein.

The closest prior art to a claimed subject matter of claims 1-5, closer than either of Smith or Casas et al., is a protease-encoding nucleic acid sequence that Nagase et al. reported in 1997 in an article in **DNA Research**, made of record herewith. Nagase et al., however, did not specifically identify any important structural features of the protease until their analysis and entry of its amino acid sequence in October 2001 under Accession No. O15072 in the SwissProt database, made of record herewith. The amino acid sequence of the human ADAM-TS3 precursor disclosed by Nagase et al. shares 52% identity with that of SEQ ID NO:2 herein, its nucleic acid sequence cannot encode either of SEQ IDs NOs:20 or 22, and its encoding DNA cannot hybridize with SEQ ID NO:19 under stringent conditions according to clause (b) of claim 2 herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached from 8:00AM-6:30PM EST on Mondays, Wednesdays, and Fridays and from 11:30AM-6:00PM EST on Tuesdays and Thursdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
August 30, 2002

PONNATHAPURA ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECH